

REMARKS

This response accompanies a request for continued examination. Claims 70 and 72-77 are pending in the application. Claims 70, 73-74, and 76 are amended herein without the addition of new matter.

Interview Summary

Applicants thank examiners Popa and Woitach for the time and courtesies extended to Applicants representatives and co-inventor Dr. Philip Sass during an interview at the PTO on September 18, 2007. The outstanding rejections were discussed as well as ways to move prosecution forward in this case.

Rejections under 35 U.S.C. §112, second paragraph

Claims 70 and 72-77 stand rejected for alleged indefiniteness. Applicants disagree with the rejection, but it is believed that the amendments to the claims obviate this rejection.

Rejections under 35 U.S.C. §112, first paragraph

Claims 70 and 72-77 stand rejected for alleged failure to comply with the written description requirement. The examiner maintains that insufficient dominant negative mutants were described to justify claims to the genus. Applicants traverse.

As demonstrated in the Nicolaides reference (Mol. Cell. Biol. 18:1635) at Figure 4C on page 1639, both the PMS2-134 truncation mutant and the full length PMS2 protein exhibit the mismatch repair deficiency phenotype in cells in which they were introduced. Thus, coupled with what was thus known in the art, the specification conveys to one of skill in the art that Applicants had possession of the claimed subject matter. The claimed subject matter is adequately described and withdrawal of the rejection is warranted.

Claims 70 and 72-77 stand rejected as allegedly not enabled by the specification. The examiner maintains that only one dominant negative mutant of human PMS2, hPMS2-134 is enabled. Applicants traverse.

The PMS2-134 truncation mutant and the full length PMS2 protein elicit mismatch repair deficiency phenotype in cells. In addition, the specification provides detailed guidance

for assessing defective mismatch repair (see, *e.g.*, Example 1). Applicants submit that multiple modes to practice the claimed invention have been provided. It would not constitute undue experimentation to determine if a polynucleotide comprise *PMS2-134* and determine the expression product of the polynucleotide inhibits mismatch repair, particularly in light of what was known in the art and the guidance provided by the specification. The claimed subject matter is thus fully enabled by the specification, and withdrawal of the rejection is warranted.

Double Patenting Rejections

Claims 70 and 73-77 stand rejected on the grounds of alleged obviousness-type double patenting over U.S. Pat. No. 6,146,894 in view of the Parkhurst reference. The 6,146,894 patent is not co-owned by Applicants, and thus is not a proper reference for obviousness-type double patenting purposes. See MPEP 804. Withdrawal of the rejection is requested.

Claims 70 and 72-77 stand rejected on the grounds of alleged obviousness-type double patenting over U.S. Pat. No. 6,808,894 in view of the Parkhurst reference. Applicants disagree with the rejection, but submit herewith a terminal disclaimer over the 6,808,894 patent. Withdrawal of the rejection is requested.

Claims 70 and 72-77 stand rejected on the grounds of alleged obviousness-type double patenting over U.S. Pat. No. 6,825,038 in view of the Parkhurst reference. Applicants disagree with the rejection, but submit herewith a terminal disclaimer over the 6,825,038 patent. Withdrawal of the rejection is requested.

Claims 70 and 72-77 stand rejected on the grounds of alleged obviousness-type double patenting over U.S. Pat. No. 6,737,268 in view of the Parkhurst reference. Applicants disagree with the rejection, but submit herewith a terminal disclaimer over the 6,737,268 patent. Withdrawal of the rejection is requested.

Rejections under 35 U.S.C. §102

It is noted that for each rejection under 35 U.S.C. §102, the office action indicates that the rejection is grounded in the interpretation that the genetically stable cell is the cell comprising the truncated dominant negative PMS2, wherein the stability of the cell is

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37 CFR § 1.116**

restored. Applicants disagree with the rejection and the rationale behind the rejection. Solely to advance prosecution, Applicants have amended the claim to indicate that genetically stable cell is a second cell. It is believed that the claim amendments thus obviate the following rejections:

- (A) Rejection of claims 70, 73-75, and 77 under 35 U.S.C. §102(b) for alleged anticipated by the Nicolaides reference (Mol. Cell. Biol. 18:1635) as evidenced by the Parkhurst reference.
- (B) Rejection of claims 70 and 73-77 under 35 U.S.C. §102(e) for alleged anticipation by U.S. Pat. No. 6,146,894 as evidenced by the Parkhurst reference.

Rejections under 35 U.S.C. §103

It is noted that for each rejection under 35 U.S.C. §103, the office action indicates that the rejection is grounded in the interpretation that the genetically stable cell is the cell comprising the truncated dominant negative PMS2, wherein the stability of the cell is restored. Applicants disagree with the rejection and the rationale behind the rejection. It is believed that the claim amendments thus obviate the following rejections:

- (A) Rejection of claims 70 and 72-77 under 35 U.S.C. §103(a) for alleged obviousness over the Nicolaides reference (Mol. Cell. Biol. 18:1635) in view of U.S. Pat. No. 6,825,038 and the Parkhurst reference.
- (B) Rejection of claims 70 and 73-77 under 35 U.S.C. §103(a) for alleged obviousness over U.S. Pat. No. 6,146,894 and the Parkhurst reference.

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Conclusion

The foregoing is a *bona fide* attempt to advance prosecution of this application to allowance. Applicants request entry of this amendment, and a favorable reconsideration of the various rejections in the office action. A notice of allowance is earnestly requested.

Respectfully Submitted,

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